

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	DATA	A MATRIX			
Date: April 9, 2018 Applicant's/Registrant's Name & Address Oxitec Ltd: 71 Innovation Drive, Milton Park Abingdon, Oxfordshire OX14 4RQ, United Kingdom			EPA Reg No./File Symbol Product OX513A Aedes aegypti	93167-EUP-R	Page 1 of
	epressible Transactivator Protein Variant (tTA	(V) and Related	Genetic Material from OX51	3A Aedes aegypti	
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
380.1100, 880.1200, 880.1400, 830.1700, 830.1750, 830.1800	Product Identity and Composition, Description of Starting Materials, Production and Formulation Process, Discussion of the Formation of Impurities, Preliminary Analysis, Certified Limits, and Enforcement Analytical Method	50443501	Oxitec Ltd.	OWN	
880.1100, 880.1200, 880.1400, 830.1700, 830.1750, 830.1800	Product Identity and Composition, Description of Starting Materials, Production and Formulation Process, Discussion of the Formation of Impurities, Preliminary Analysis, Certified Limits, and Enforcement Analytical Method	50560402	Oxitec Ltd.	own	Submitted herein.
870.1100	Acute Oral Toxicity	50443502	Oxitec Ltd.	OWN	
870.1100	Acute Oral Toxicity	50560403	Oxitec Ltd.	OWN	Submitted herein.
370.1300	Acute Inhalation Toxicity	50443503	Oxitec Ltd.	OWN	
870.1300	Acute Inhalation Toxicity	50560404	Oxitec Ltd.	OWN	Submitted herein.
870.2400	Primary Eye Irritation	50443504	Oxitec Ltd.	OWN	
Signature			Name and Title  Keith A. Matthews (Agent) Wiley Rein LLP		Date 4-9-18

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	DATA	MATRIX			
Date: April 9, 2018			EPA Reg No./File Symbol 93	167-EUP-R	Page 2 of 4
Applicant's/Registrant's Name & Address Oxitec Ltd. 71 Innovation Drive, Milton Park Abingdon, Oxfordshire OX14 4RQ, United Kingdom			Product OX513A Aedes aegypti		
Ingredient Tetracycline-R	epressible Transactivator Protein Variant (tTA	V) and Related	Genetic Material from OX513A A	edes aegypti	
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.2400	Primary Eye Irritation	50560405	Oxitec Ltd.	OWN	Submitted herein.
870.2500	Primary Dermal Irritation	50443505	Oxitec Ltd.	OWN	
870.2500	Primary Dermal Irritation	50560406	Oxitec Ltd.	OWN	Submitted herein.
None	Hypersensitivity Incidents	50443506	Oxitec Ltd.	OWN	
850.1010	Freshwater Invertebrate LC <sub>50</sub>	50443507	Oxitec Ltd.	OWN	
850.1075	Fish Acute Oral Toxicity, Freshwater	50326401	Oxitec Ltd.	OWN	
850.2100	Avian Acute Oral Toxicity	50443508	Oxitec Ltd.	OWN	
850.2200	Avian Dietary Toxicity	50443509	Oxitec Ltd.	OWN	
850.4100	Terrestrial Plant Toxicity (Seedling Emergence)	50443510	Oxitec Ltd.	OWN	
850.4150	Terrestrial Plant Toxicity (Vegetative Vigor)	50443511	Oxitec Ltd.	OWN	
880.4350	Nontarget Insect Testing	50443512	Oxitec Ltd.	OWN	

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	Name and Title  Keith A. Matthews (Agent) Wiley Rein LLP  Date  4-9-18

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		Product OX513A Aedes aegypti			
	epressible Transactivator Protein Variant (tTA	the state of the s			
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.1100; 870.1300; 870.2400; 870.2500; 850.2100; 850.2200; 850.4100; 850.4150; 850.4350	Published Literature Cited in Support of Acute Toxicity and Nontarget Organism Waivers, Endangered Species Assessment, Effects of Environmental Exposure to Tetracycline Document, Bioinformatics Predicted Protein Data, and Arbovirus Testing in OX513A Samples	50443517	Oxitec Ltd.	OWN	
	Bioinformatics Analysis (2013)	50326402	Oxitec Ltd.	OWN	
	Bioinformatics Analysis (2017)	50326403	Oxitec Ltd.	OWN	
	Western Blot Analysis of Aedes aegypti OX513A Saliva	50326404	Oxitec Ltd.	OWN	
	Environmental Assessment (FDA)	50443513	Oxitec Ltd.	OWN	
	Endangered Species Assessment	50443514	Oxitec Ltd.	OWN	
The state of the s	Effects of Environmental Exposure to Tetracycline	50443515	Oxitec Ltd.	OWN	

Signature  Name and Title  Keith A. Matthews (Agent) Wiley Rein LLP	Date 4-9-18

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		Product OX513A Aedes aegypti		
		Coldinate and an expension of the Control of the Co		
Guideline Study Name	MRID Number	Submitter	Status	Note
Bioinformatics Analysis for Protein Digestibility, Environmental Degradation, Cell Membrane Permeability	50443516	Oxitec Ltd	OWN	
Arbovirus Testing in OX513A Samples	50443518	Oxitec Ltd.	OWN	
On-Breeding Phenotype of Surviving OX513A Reared in the Absence of Tetracycline	50443519	Oxitec Ltd.	OWN	
Protein Report – Expressed Protein Quantities	50560407	Oxitec Ltd.	own	Submitted herein.
Protein Report – Expressed Protein Quantities	50465113	Oxitec Ltd.	OWN	
Protein Report – Digestion	50465114	Oxitec Ltd.	OWN	
Oxitec's Response to EPA's 90-Day Preliminary Technical Screen	50560401	Oxitec Ltd.	OWN	Submitted herein.
Assessment of Heterozygous OX513A Individuals Surviving Without Provision of Tetracycline in the Diet	50560408	Oxitec Ltd.	OWN	Submitted herein.
Arbovirus Testing in OX513A Samples	50560409	Oxitec Ltd.	OWN	Submitted herein.
	Repressible Transactivator Protein Variant (tTA)  Guideline Study Name  Bioinformatics Analysis for Protein Digestibility, Environmental Degradation, Cell Membrane Permeability  Arbovirus Testing in OX513A Samples  On-Breeding Phenotype of Surviving OX513A Reared in the Absence of Tetracycline Protein Report – Expressed Protein Quantities  Protein Report – Digestion  Oxitec's Response to EPA's 90-Day Preliminary Technical Screen  Assessment of Heterozygous OX513A Individuals Surviving Without Provision of Tetracycline in the Diet	Repressible Transactivator Protein Variant (tTAV) and Related  Guideline Study Name  Bioinformatics Analysis for Protein Digestibility, Environmental Degradation, Cell Membrane Permeability  Arbovirus Testing in OX513A Samples  On-Breeding Phenotype of Surviving OX513A Reared in the Absence of Tetracycline  Protein Report – Expressed Protein Quantities  Protein Report – Digestion  Oxitec's Response to EPA's 90-Day Preliminary Technical Screen  Assessment of Heterozygous OX513A Individuals Surviving Without Provision of Tetracycline in the Diet	EPA Reg No./File Symbol 93   Product	EPA Reg No./File Symbol 93167-EUP-R Product OX513A Aedes aegypti  Q. United Kingdom  Repressible Transactivator Protein Variant (tTAV) and Related Genetic Material from OX513A Aedes aegypti  Guideline Study Name MRID Number Submitter Status  Bioinformatics Analysis for Protein Digestibility, Environmental Degradation, Cell Membrane Permeability Arbovirus Testing in OX513A Samples 50443518 Oxitec Ltd. OWN  On-Breeding Phenotype of Surviving OX513A Reared in the Absence of Tetracycline Protein Report – Expressed Protein Quantities 50560407 Oxitec Ltd. OWN  Protein Report – Expressed Protein Quantities 50465113 Oxitec Ltd. OWN  Protein Report – Digestion 50465114 Oxitec Ltd. OWN  Oxitec's Response to EPA's 90-Day Preliminary Technical Screen  Assessment of Heterozygous OX513A Individuals Surviving Without Provision of Tetracycline in the Diet

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